

Exhibit 1

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE: Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates to

All Cases

**LETTER OF REQUEST FOR
INTERNATIONAL JUDICIAL
ASSISTANCE TO THE
APPROPRIATE JUDICIAL
AUTHORITIES IN THE UNITED
KINGDOM**

The United States District Court for the District of Minnesota presents its compliments to the Senior Master of the High Court of Justice, Queen's Bench Division, Royal Courts of Justice, Strand, London WC2A 2LL and requests international judicial assistance for testimony and the production of documents to be used in a civil proceeding before this Court in the above-captioned matter. This Court requests the assistance described herein as necessary in the interests of justice. The assistance requested is for the appropriate judicial authority of the United Kingdom to compel the below-named individual to submit to a deposition and produce documents.

- Dr. Andrew Hamer, Royal Hallamshire/Sheffield Teaching Hospital Trust/Sheffield Orthopedics Limited, Glossop Rd, Sheffield, South Yorkshire S10 2JF / 401 Sandygate Road, Sheffield S10 5UB

Dr. Hamer is a nonparty to the above-captioned litigation and is material and necessary to aid in the resolution of the matter.

This Court affirms that:

1. This Letter of Request is sent to the High Court of Justice, Queen's Bench Division, by the United States District Court for the District of Minnesota pursuant to, and in conformity with 28 U.S.C. § 1781, Article III of the Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, the Hague, 18 March 1970, the Evidence (Proceedings in Other Jurisdictions) Act 1975, and Part 34 of the English Civil Procedure Rules;

2. The requesting Court is a competent court in both law and equity, has jurisdiction over this action, and has the authority to compel the appearance of and the production of documents by corporations and individuals within its jurisdiction;

3. This request is issued pursuant to the rules and procedures applicable within this Court's jurisdiction; and

4. The testimony and documents sought are relevant to the matters at issue in this action, are anticipated to be used at trial, are not available from any other source, and cannot be obtained without the assistance of the judicial authority of the United Kingdom.

In light of international law and the comity that exists between the United States and the United Kingdom, the undersigned respectfully issues this Letter of Request for international assistance. The requesting Court provides the additional information below in support of its request.

I. **THE PARTIES AND THEIR REPRESENTATIVES**

The defendants are 3M™ and Arizant Healthcare Inc. (“Defendants”), the designers and manufacturers of the Bair Hugger™ patient warming system (“Bair Hugger system”). Defendants are represented by:

Jerry W. Blackwell, Corey L. Gordon, and Peter J. Goss of Blackwell Burke, P.A., 431 South Seventh Street, Suite 2500, Minneapolis, MN 55415.

Bridget M. Ahmann and Christin Eaton Garcia of Faegre Baker Daniels LLP, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, MN 55402.

The plaintiffs (“Plaintiffs”) in the proceedings are patients who allegedly suffered infections while receiving surgical warming from the Bair Hugger system. Plaintiffs are represented by:

Co-Lead Counsel:

Michael V. Ciresi and Jan M. Conlin of Ciresi Conlin, LLP, 225 S. 6th St., Suite 4600, Minneapolis, MN 55402;

Anthony J. Nemo and Genevieve M. Zimmerman of Meshbesher & Spence LTD, 1616 Park Avenue South, Minneapolis, MN 55404;

Ben W. Gordon, J. Michael Papantonio of Levin Papantonio, P.A., 316 S. Baylen Street, Suite 600, Pensacola, FL 32502-5996.

II. **BACKGROUND**

The Plaintiffs in this MDL litigation are patients who allegedly have experienced post-surgical infections and/or other medical complications following orthopedic or general surgery where a Bair Hugger™ patient warming system (“Bair Hugger system”) was used. [Master Long-Form Complaint, ¶¶ 20, 22, attached hereto as Exhibit 1] The

Bair Hugger system is an FDA-cleared medical device used to warm patients during surgery in order to maintain the patient's normal body temperature. Plaintiffs allege that the Bair Hugger system caused their post-surgical infections and seek personal injury recovery against Defendants, who Plaintiffs allege designed, manufactured and marketed the Bair Hugger system used in their respective surgeries. [Master Long-Form Complaint, ¶¶ 23, 24]

In support of their allegations, Plaintiffs specifically cite to and rely on a number of scientific studies that allegedly "document[] the adverse effects of the Bair Hugger." *Id.* at ¶¶ 62-63. These studies were authored by individuals residing in the United States, as well as individuals residing in the United Kingdom ("U.K."). Defendants contend that they are entitled to discover any information these authors have about the studies relied upon by Plaintiffs, because the study authors themselves disclaim any proof of causation within the context of any particular study.

III. THE AUTHOR'S RELATIONSHIP WITH PLAINTIFFS AND DEFENDANTS

Dr. Hamer conducted research and published scientific studies relied upon by Plaintiffs in their suit against Defendants. Plaintiffs' Master Long-Form Complaint specifically cites to these studies in support of their position that such studies "document[] the adverse effects of the Bair Hugger." [Master Long-Form Complaint, ¶ 62] Certain of these studies were also discussed by Plaintiffs' counsel and witnesses during Plaintiffs' presentation at a Science Day before this Court. Plaintiffs will likely attempt to use these studies as evidence at trial. The Defendants plan to use these studies

to support their defense that the Plaintiffs lack scientific evidence that the Bair Hugger warming blanket causes or increases the risk of surgical site infections.

IV. REQUESTED EVIDENCE

In support of their defense in this lawsuit, Defendants request the following evidence from Dr. Hamer:

1. To take the testimony of Dr. Hamer on the topics specific in the attached Appendix A;
2. The disclosure of documents specified within the attached Appendix B, which are believed to be in the possession of Dr. Hamer.

Defendants contend that the study authors specifically deny that their studies establish that the Bair Hugger warming blanket causes surgical site infections. Because Plaintiffs rely on these studies to support their claims, Defendants submit that information in the possession of Dr. Hamer about the design, procedures, conduct, data, and findings from the various scientific studies is highly relevant to this dispute and the proper subject of the letters rogatory process. On information and belief, Dr. Hamer possesses documents about design, procedures, conduct, data, and findings from their studies.

After review, this Court has concluded that it is appropriate to seek international judicial assistance to facilitate the production of the requested documents because the requested documents are relevant, are anticipated to be used at trial, are not available from any other source and cannot be obtained without the assistance of the judicial authorities of the United Kingdom.

V. PARTICIPATION IN DEPOSITIONS BY U.S. COUNSEL IS REQUESTED

Defendants request that you permit the questioning of the witnesses by the trial counsel in the action before this Court, as listed above. Defendants also request that all original documents provided pursuant to this process be produced for inspection by the Parties at the offices of Faegre Baker Daniels, 7 Pilgrim Street, London, EC4V 6LB, England, or some other place mutually agreeable to the parties, seven days prior to the depositions of witnesses.

Defendants further request that the Court issue its decision on this Request, and notice of the time and place for examination of the witnesses and the production of documents, to this Court and to counsel for Defendants as indicated above. Defendants further request that you order the examination under oath and appoint an Examiner to oversee the examination of the witnesses concerning the matters listed in the attached Appendix A at a place and time to be determined by the Examiner.

VI. DISCUSSION

The United Kingdom and the United States are both signatories to the Hague Convention. The Study Author, Dr. Hamer, in question here is not a party to this litigation, is believed to be a citizen and resident of the United Kingdom and not subject to the jurisdiction of this Court. Thus, the procedures of the Hague Convention are the only means by which the requested evidence may be obtained.

The Court finds that letters rogatory are appropriate in this case because the requests are narrowly tailored to information that is relevant to its defense and necessary

for the presentation of its case. These requests are described in full in the attached appendices.

The evidence that the Defendants seek from Dr. Hamer is not available from other sources. The documents requested are Dr. Hamer's own documents and records. These documents are specific to, and in the exclusive possession of, these individuals. Therefore, in the interests of justice, international judicial assistance is needed to assure the production of this evidence from Dr. Hamer.

VII. REIMBURSEMENT OF COSTS

The Defendants agree to pay and undertake to reimburse any costs and expenses associated with this Request incurred by the Court in executing the same, as well as all reasonable costs and expenses associated with compliance by the witness with the Court's Order to the extent permitted or allowed under your law and procedure, or which the Court otherwise deems required under the circumstances.

VIII. RECIPROCITY

The requesting Court stands ready and willing to do the same for the courts of the United Kingdom if and when requested.

Dated: _____, 2016

The Honorable Joan N. Erickson
United States District Judge
District of Minnesota

**Appendix A for Dr. Andrew Hamer
Testimony To Be Given**

Background

1. Name, address, and date of birth.
2. Education and employment history.
3. Use of and knowledge about patient warming devices.
4. Factors that influence infection for general and orthopedic surgery.
5. Infection control practices.
6. Experience designing, conducting, and writing manuscripts for the following studies:
 - “Do forced air patient-warming devices disrupt unidirectional downward airflow?,” published in the Journal of Bone & Joint Surgery (Britain), 2012 Feb;94(2):254-6 (hereafter “Legg, Cannon, & Hamer”).
 - “Forced-air patient warming blankets disrupt unidirectional airflow” in the Bone & Joint Journal, 2013 Mar.; 95-B(3):407-10 (hereafter “Legg & Hamer”).

Roles and Arrangements for the Studies Described in Legg, Cannon, & Hamer and Legg & Hamer

7. Your role in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
8. The identity of and roles played by others in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
9. Communications with others involved in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
10. Communications with Dr. Scott Augustine about the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
11. Communications with Augustine Temperature Management about the studies described in Legg, Cannon, & Hamer and Legg & Hamer.

12. Communications with the hospitals and locations where the studies described in Legg, Cannon, & Hamer and Legg & Hamer were performed.

Design, Materials, and Methods for the Studies Described in McGovern et al., Belani et al., and Reed et al.

13. Details of and reasons for selecting locations, protocols, procedures, materials, and methods used in the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
14. Selection, procurement, and condition of the operating theatres, patient warming devices, and other equipment used in the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
15. Proposed and final study designs for the studies described in Legg, Cannon, & Hamer and Legg & Hamer, and the rationales for changes to study designs and protocols.
16. The carrying out of the studies described in Legg, Cannon, & Hamer and Legg & Hamer, and changes to protocols and practices during the conduct of those studies.
17. All measurements taken and data collected in the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
18. Photographs or video recordings taken in connection with the studies described in Legg, Cannon, & Hamer and Legg & Hamer.

Study Results and Analysis

19. Statistical analysis of the raw data obtained in the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
20. Preparation of the manuscripts for Legg, Cannon, & Hamer and Legg & Hamer, including the roles of co-authors.
21. Reviewer comments for Legg, Cannon, & Hamer and Legg & Hamer, including communications with co-authors regarding reactions and responses to reviewer comments.
22. Interpretation of the results of Legg, Cannon, & Hamer and Legg & Hamer.
23. Application of results of Legg, Cannon, & Hamer and Legg & Hamer to hospital practices and patient safety.
24. Limitations of the designs, results, and conclusions of Legg, Cannon, & Hamer and Legg & Hamer.

Information About Other Studies

25. Information about the funding, selection of operating rooms, selection and procurement of patient warming devices, condition of patient warming devices, arrangements, design, conduct, results, analysis or publication of the studies described in these articles:

- Albrecht, M., et. al. Forced-air warming: a source of airborne contamination in the operating room? *Orthopedic Rev.* 2009; 1:e28
- Albrecht, M., et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2011; 39:321-28
- Dasari, K., et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012; 67:244-49
- McGovern, P., et al. Forced-air warming and ultra-clean ventilation do not mix: an investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics. *J Bone Joint Surg. (Br.)* 2011; 93(11):1537-44
- Belani, K., et al., Patient warming excess heat: the effects on orthopedic operating room ventilation performance. *Anesthesia Analgesia* 2013; 117(2):406-11
- Reed, M., et al. Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions. *AANA J* 2013; 81(4):275-80.
- Wood, A.,et al. Infection control hazards associated with the use of forced-air warming in operating theatres. *J Hosp Infect.* 2014;1-9

Appendix B-2
Request for Documents to Andrew Hamer

Defendants 3M Company and Arizant Healthcare, Inc. request that the documents described below be produced by Dr. Hamer.

Documents To Be Produced

Dr. Hamer's Background

1. Your curriculum vitae or resume.

Documents Relating to Study Initiation and Protocols, Materials, and Methods

2. Communications between and among you, A. Legg, and T. Cannon regarding the study that was described in the article titled “Do forced air patient-warming devices disrupt unidirectional downward airflow?,” published in the Journal of Bone & Joint Surgery (Britain), 2012 Feb;94(2):254-6 (hereafter “Legg, Cannon, & Hamer”).
3. Communications between you and A. Legg regarding the study that was described in the article titled “Forced-air patient warming blankets disrupt unidirectional airflow” in the Bone & Joint Journal, 2013 Mar.; 95-B(3):407-10 (hereafter “Legg & Hamer”).
4. Communications between and among you and A. Legg on the subject of funding for the study described in Legg & Hamer.
5. Communications between and among you, A. Legg, and T. Cannon on the subject of funding for the study described in Legg, Cannon, & Hamer.
6. Communications between you and A. Legg on the subject of obtaining patient warming devices for the study described in Legg & Hamer.
7. Communications between and among you, A. Legg, and T. Cannon on the subject of obtaining patient warming devices for the study described in Legg, Cannon, & Hamer.
8. Communications between you and A. Legg on the subject of the design of the study described in Legg & Hamer.
9. Communications between and among and you, A. Legg, and T. Cannon on the subject of the design of the study described in Legg, Cannon, & Hamer.
10. Communications between you and Scott Augustine on the subject of the design of the study described in Legg & Hamer.
11. Communications between you and Scott Augustine on the subject of the design of the study described in Legg, Cannon, & Hamer.

12. Communications between you and Augustine Biomedical + Design on the subject of the design of the study described in Legg & Hamer.
13. Communications between you and Augustine Biomedical + Design on the subject of the design of the study described in Legg, Cannon, & Hamer.
14. Communications between you and Augustine Temperature Management LLC on the subject of the design of the study described in Legg & Hamer.
15. Communications between you and Augustine Temperature Management LLC on the subject of the design of the study described in Legg, Cannon, & Hamer.
16. Communications between you and Scott Augustine on the subject of funding of the study described in Legg & Hamer.
17. Communications between you and Scott Augustine on the subject of funding of the study described in Legg, Cannon, & Hamer.
18. Communications between you and Augustine Biomedical + Design on the subject of funding of the study described in Legg & Hamer.
19. Communications between you and Augustine Biomedical + Design on the subject of funding of the study described in Legg, Cannon, & Hamer.
20. Communications between you and Augustine Temperature Management LLC on the subject of funding of the study described in Legg & Hamer.
21. Communications between you and Augustine Temperature Management LLC on the subject of funding of the study described in Legg, Cannon, & Hamer.
22. Communications between you and Scott Augustine regarding the implementation of the study described in Legg & Hamer.
23. Communications between you and Scott Augustine regarding the implementation of the study described in Legg, Cannon, & Hamer.
24. Communications between you and Augustine Biomedical + Design regarding the implementation of the study described in Legg & Hamer.
25. Communications between you and Augustine Biomedical + Design regarding the implementation of the study described in Legg, Cannon, & Hamer.
26. Communications between you and Augustine Temperature Management LLC regarding the implementation of the study described in Legg & Hamer.

27. Communications between you and Augustine Temperature Management LLC regarding the implementation of the study described in Legg, Cannon, & Hamer.
28. Communications between you and Northern General Hospital, Sheffield, UK regarding the study described in Legg & Hamer.
29. Communications between you and Northern General Hospital, Sheffield, UK regarding the study described in Legg, Cannon, & Hamer.
30. Model and serial numbers for the patient warming devices used in the study described in Legg & Hamer.
31. Model and serial numbers for the patient warming devices used in the study described in Legg, Cannon, & Hamer.
32. Specifications of the ventilation system for the operating room used in the study described in Legg & Hamer.
33. Specifications of the ventilation system for the operating room used in the study described in Legg, Cannon, & Hamer.
34. Specifications, instructions for use, and calibration records for the particle counter used in the study described in Legg & Hamer.
35. Specifications, instructions for use, and calibration records for the particle counter used in the study described in Legg, Cannon, & Hamer.
36. Specifications and instructions for use of the bubble generator used in the study described in Legg & Hamer.
37. Draft protocols for the study described in Legg & Hamer, including but not limited to the arrangement of the patient, draping, lights, and personnel.
38. Draft protocols for the study described in Legg, Cannon, & Hamer, including but not limited to the arrangement of the patient, draping, lights, and personnel.
39. Final protocols for the study described in Legg & Hamer, including but not limited to the arrangement of the patient, draping, lights, and personnel.
40. Final protocols for the study described in Legg, Cannon, & Hamer, including but not limited to the arrangement of the patient, draping, lights, and personnel.
41. Patient warming protocols and warming technologies employed at the Northern General Hospital, Sheffield, UK from 2008 to the present.

42. Orthopaedic infection rates at the Northern General Hospital, Sheffield, UK from 2008 to the present.

Data from and Results of the Studies

43. All raw data generated during the implementation of the study described in Legg & Hamer.
44. All raw data generated during the implementation of the study described in Legg, Cannon, & Hamer.
45. All results from the statistical analysis of raw data from the study described in Legg & Hamer.
46. All results from the statistical analysis of raw data from the study described in Legg, Cannon, & Hamer.
47. Photographs, including time-lapse photography, taken during the implementation of the study described in Legg & Hamer.
48. Photographs, including time-lapse photography, taken during the implementation of the study described in Legg, Cannon, & Hamer.
49. Video or audio recordings made during the implementation of the study described in Legg & Hamer.
50. Video or audio recordings made during the implementation of the study described in Legg, Cannon, & Hamer.
51. Communications between you and A. Legg regarding the results of the study described in Legg & Hamer.
52. Communications between and among you and the other authors of Legg, Cannon, & Hamer regarding the results of the study described in Legg, Cannon, & Hamer.
53. Communications between you and Scott Augustine regarding the results of the study described in Legg & Hamer.
54. Communications between you and Scott Augustine regarding the results of the study described in Legg, Cannon, & Hamer.
55. Communications between you and Augustine Biomedical + Design regarding the results of the study described in Legg & Hamer.
56. Communications between you and Augustine Biomedical + Design regarding the results of the study described in Legg, Cannon, & Hamer.

57. Communications between you and Augustine Temperature Management LLC regarding the results of the study described in Legg & Hamer.
58. Communications between you and Augustine Temperature Management LLC regarding the results of the study described in Legg, Cannon, & Hamer.

Study Publication

59. All pre-publication drafts and manuscripts of Legg & Hamer.
60. All pre-publication drafts and manuscripts of Legg, Cannon, & Hamer.
61. Communications between you and A. Legg regarding the drafting of Legg & Hamer.
62. Communications between and among you and the other authors of Legg, Cannon, & Hamer regarding the drafting of Legg, Cannon, & Hamer.
63. Communications between you and Scott Augustine regarding the drafting of Legg & Hamer.
64. Communications between you and Scott Augustine regarding the drafting of Legg, Cannon, & Hamer.
65. All communications from reviewers of Legg & Hamer regarding Legg & Hamer.
66. All communications from reviewers of Legg, Cannon, & Hamer regarding Legg, Cannon, & Hamer.

Documents Relating to Consulting Fees (If Any) Received From Scott Augustine, Augustine Biomedical + Design, and/or Augustine Temperature Management LLC

67. Records of consulting fees, expense reimbursement, and other compensation paid to you by Scott Augustine.
68. Records of consulting fees, expense reimbursement, and other compensation paid to you by Augustine Biomedical + Design.
69. Records of consulting fees, expense reimbursement, and other compensation paid to you by Augustine Temperature Management LLC.

Communications with Counsel

70. Communications or correspondence between you and any lawyer or solicitor representing 3M in connection with the subject litigation pending in the United States.

71. Communications or correspondence between you and any lawyer or solicitor representing any plaintiff in connection with the subject litigation pending in the United States.